

Phase 2 (and 1/2) Concepts OEWG Timeline

OEWG timeline for opening a trial to enrollment, for NCTN Phase 2 (and 1/2) Concepts:

Absolute deadline: 450 days

NCTN Phase 2 (and 1/2) Concepts include the following:

- NCTN phase 2 (or 1/2) Concepts

Phase 2 concept approval stage: 60 days (Day 1 – 60)

Protocol authoring stage: 60 days (Day 60 – 120)

Protocol approval and open to enrollment: 330 days (Day 120 – 450)

(Please see timeline flowchart on next slide.)

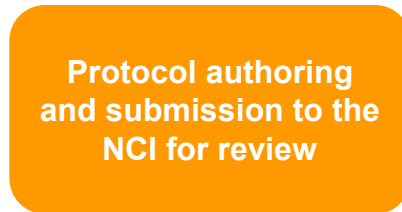
Stage 1: Concept approval

Target = 60 days



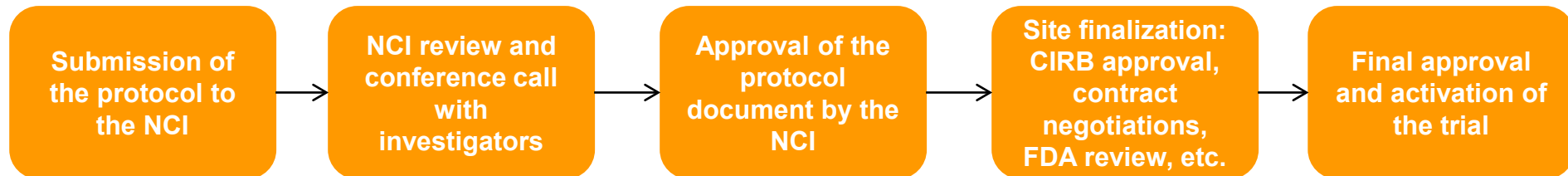
Stage 2: Protocol submission

Target = 60 days



Stage 3: Protocol Approval and Activation

Target = 330 days



Absolute deadline for opening trial to enrollment is 450 calendar days